REMARKS

Claims 1-10, 20 and 22 are currently pending in the application. Claim 1 is amended. Claim 8 is cancelled. No new matter is added.

Applicants would first like to thank Examiner Li for taking the time to discuss the outstanding rejections with Applicants' representatives on December 11, 2006, and again May 29, 2007. During the interview, Applicants' representatives presented the arguments set out below. Examiner Li maintained that regardless of the functional limitations in the claim, and the fact that the sequences taught in the prior art do not possess the claimed function, the prior art nonetheless inherently anticipated the claims.

Rejection of Claims 1-5 and 20 Under 35 U.S.C. §102(b)

The Office Action states that claims 1-5 and 20 are rejected under §102(b) as allegedly anticipated by Nagpal et al. Applicants respectfully traverse.

It is black letter law that anticipation requires that the purported prior art reference disclose each and every limitation of the claim. *Atlas Powder Company et al. v. IRECO, Incorporated et al.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999).

The instant claims require two primary elements: (1) an isolated polypeptide comprising the amino acid sequence N1N2X1X2X3N3X4N4X5 and (2) that the claimed polypeptide bind specifically to a ChemerinR polypeptide. The inclusion of the functional requirement of ChemerinR specific binding reduces the scope of the claim beyond what would otherwise be encompassed by the recitation of the polypeptide alone. That is, because the claim expressly requires structure and function, it is narrower than if the claim required structure alone. Thus, to anticipate the claim, a single prior art reference must teach both elements: structure and function.

Nagpal et al. do not teach a polypeptide comprising all the limitations of the polypeptides instantly claimed. Specifically Nagpal et al does not teach a polypeptide that binds specifically to a ChemerinR polypeptide, as required by claim 1 and its dependent claims.

Though the 163 amino acid polypeptide taught by Nagpal et al. comprises SEQ ID NO:61, i.e. the elected species, the polypeptide taught by Nagpal et al. does not bind specifically to a ChemerinR polypeptide, as required by claim 1 and its dependent claims.

As disclosed herein, human chemerin is encoded by the Tazarotene-induced Gene 2, (TIG2), and is synthesized as a 163 amino acid precursor molecule (SEQ ID NO:8) that contains a hydrophobic 20 amino acid N-terminal sequence prosegment and a six amino acid C-terminal prosegment. During processing of the precursor molecule, both its N-terminal residue 20 amino acid hydrophobic segment and its C-terminal six residues are by proteolytically cleaved, giving rise to a Chemerin (SEQ ID NO:14), a monomeric bioactive molecule that binds to the G-protein coupled receptor ChemR23 (Chemerin receptor).

The claimed binding bioactivity is concentrated in the nine residues which precede the six amino acid C-terminal prosegment of the human chemerin precursor (SEQ ID NO:8). These nine residues preceding the six amino acid C-terminal prosegment have an amino acid sequence of YFPGQFAFS (SEQ ID NO:61), the elected species. The presence of the six amino acid C-terminal prosegment blocks the claimed binding bioactivity. Therefore, the presence of the six amino acid C-terminal prosegment in the 163 amino acid human Chemerin precursor polypeptide (SEQ ID NO:8) taught by Nagpal et al. precludes its ability to meet the specific binding activity required by the instant claims.

The specification defines "specifically binds" as meaning that the Chemerin polypeptide has an EC_{50}, IC_{50},or a K_d of 100nM or less (paragraph 0091 of the published application). The prochemerin polypeptide taught by the prior art does not have this activity, and therefore does not meet this express limitation of the claim. The specification teaches assays using various truncated forms of the C-terminal end of Chemerin, and shows that the C-terminal end of prochemerin (having the 6 C-terminal residues) "was not able to activate the receptor under high concentration" (EC_{50} of 160 μM) whereas the C-terminal fragment having the sequence of SEQ ID NO: 61 activated the receptor with high affinity (EC_{50} 7 nM). The specification also teaches that recombinant prochemerin (i.e., the full length propeptide) had an EC_{50} of 393 nM; that is, it

does not specifically bind to ChemerinR; in comparison with the recombinant Chemerin (EC_{50} 4.5 nM) which specifically binds to ChemerinR.

While Applicants understand that a prior art reference may anticipate a functional limitation if the prior art inherently teaches, but did not recognize, the functional limitation. This is not the case here. Applicants have demonstrated that the polypeptide taught by Nagpal et al. does not meet the claimed functional limitation. The only way, therefore, for Nagpal et al. to anticipate the claimed invention is to read the functional limitation out of the instant claims. Applicants are not aware of any law or court precedence that would permit the Examiner to ignore an express limitation of the claims in order to reach a finding of anticipation. If the Examiner believes that the rejection should be maintained in view of Applicants' response, Applicants request that the Examiner cite case law or specific support from the MPEP that states that express limitations in a claim can be ignored in order to reach a finding of anticipation.

Nagpal et al.'s teaching of a human sequcne corresponding to the chemerin precursor polypeptide is not anticipatory because the polypeptide taught by Nagpal et al. does not bind specifically to a ChemerinR polypeptide, as required by claim 1 and its dependent claims.

During the May 29, 2007 discussion, Applicants' representative pointed out to the Examiner the exact passages in the instant application that demonstrate that the peptide taught in the prior art does not specifically bind to the claimed receptor. The Examiner was unable to indicate to Applicants' representative where the prior art taught the claimed functional limitation, but maintained nonetheless that the prior art anticipated the claims. Applicants in no way acquiesce to the Examiner's rejection, however, in view of the Examiner's maintenance of the rejection in the face of data that clearly shows that the prior art does not meet the claimed functional limitation, Applicants have amended the claims to expedite prosecution. Support for this amendment can be found in the specification as filed, particularly at paragraph 138. Nagpal et al. do not teach a polypeptide that does not include the C-terminal sequence KALPRS. Accordingly, Applicants request reconsideration and withdrawal of the rejection.

Rejection of Claims 1-5, 10, 20, and 22 Under 35 U.S.C. §102(e)

Claims 1-5, 10, 20 and 22 are rejected under 102 (e) as being anticipated by Lal et al. US2005/0084936A1 ('936). Applicants respectfully traverse.

Applicants traverse the rejection.

It is black letter law that anticipation requires that the purported prior art reference disclose each and every limitation of the claim. *Atlas Powder Company et al. v. IRECO, Incorporated et al.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999).

The instant claims require two primary elements: (1) an isolated polypeptide comprising the amino acid sequence N1N2X1X2X3N3X4N4X5 and (2) that the claimed polypeptide bind specifically to a ChemerinR polypeptide. The inclusion of the functional requirement of ChemerinR specific binding reduces the scope of the claim beyond what would otherwise be encompassed by the recitation of the polypeptide alone. That is, because the claim expressly requires structure and function, it is narrower than if the claim required structure alone. Thus, to anticipate the claim, a single prior art reference must teach both elements: structure and function.

'936 does not teach a polypeptide comprising all the limitations of the polypeptides instantly claimed. Specifically '936 does not teach a polypeptide that binds specifically to a ChemerinR polypeptide, as required by claim 1 and its dependent claims.

Though the 163 amino acid polypeptide disclosed by '936 comprises instant SEQ ID NO:61, i.e. the elected species, the referenced polypeptide does not bind specifically to a chemerinR polypeptide, as required by claim 1 and its dependent claims.

As disclosed herein, human chemerin (encoded by the Tazarotene-induced Gene 2, (TIG2)), is synthesized as a 163 amino acid precursor molecule (SEQ ID NO:8) that contains a hydrophobic 20 amino acid N-terminal sequence prosegment and a six amino acid C-terminal prosegment. During processing of the precursor molecule, both its N-terminal residue 20 amino acid hydrophobic segment and its C-terminal six residues are proteolytically cleaved, giving rise to Chemerin (SEQ ID NO:14), a monomeric bioactive molecule that binds to the G-protein coupled receptor ChemR23 (Chemerin receptor).

The claimed binding bioactivity is concentrated in the nine residues which precede the six amino acid C-terminal prosegment of the human chemerin precursor (SEQ ID NO:8). These nine residues preceding the six amino acid C-terminal prosegment have an amino acid sequence of YFPGQFAFS (SEQ ID NO:61), the elected species. The presence of the six amino acid C-terminal prosegment blocks the claimed binding bioactivity. Therefore, the presence of the six amino acid C-terminal prosegment in the 163 amino acid human Chemerin precursor polypeptide taught by '936 precludes its ability to meet the specific binding activity required by the instant claims.

The specification defines "specifically binds" as meaning that the Chemerin polypeptide has an EC_{50}, IC_{50},or a K_d of 100nM or less (paragraph 0091 of the published application). The prochemerin polypeptide taught by the prior art does not have this activity, and therefore does not meet this express limitation of the claim. The specification teaches assays using various truncated forms of the C-terminal end of Chemerin, and shows that the C-terminal end of prochemerin (having the 6 C-terminal residues) "was not able to activate the receptor under high concentration" (EC_{50} of 160 μM) whereas the C-terminal fragment having the sequence of SEQ ID NO: 61 activated the receptor with high affinity (EC_{50} 7 nM). The specification also teaches that recombinant prochemerin (i.e., the full length propeptide) had an EC_{50} of 393 nM; that is, it does not specifically bind to ChemerinR.

While Applicants understand that a prior art reference may anticipate a functional limitation if the prior art inherently teaches, but did not recognize, the functional limitation. This is not the case here. Applicants have demonstrated that the polypeptide taught by '936 does not meet the claimed functional limitation. The only way, therefore, for '936 to anticipate the claimed invention is to read the expressly recited functional limitation out of the instant claims. Applicants are not aware of any law or court precedence that would permit the Examiner to ignore an express limitation of the claims in order to reach a finding of anticipation. If the Examiner believes that the rejection should be maintained in view of Applicants' response, Applicants request that the Examiner cite case law or specific support from the MPEP that states that express limitations in a claim can be ignored in order to reach a finding of anticipation.

The '936 teachings of the 163 amino acid polypeptide are not anticipatory because the polypeptide taught by the '936 does not bind specifically to a ChemerinR polypeptide, as required by claim 1 and its dependent claims. Moreover, as noted above, Applicants have amended claim 1 to exclude polypeptide sequences that comprise the C-terminal sequence KALPRS. Accordingly, Applicants request reconsideration and withdrawal of the rejection.

Conclusion

In the event that no further art is applied to the instant claims by the Examiner, Applicants request that the search be extended to the non elected species. Applicants contend that a search of consensus sequence SEQ ID NO:94, recited in claim 1, would encompass these nonelected species. The generic peptide of SEQ ID NO:94 is a consensus sequence derived from chemerin which confers the claimed bioactivity. Each subgenus of peptides further limits the choice of amino acids at specified residues in the consensus sequence recited in claim 1. Therefore, a search of the consensus sequence recited in claim 1 should provide for the peptides recited in the claims of ALL the restriction groups.

Applicant submits that all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicant's attorney/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney/agent of record.

Respectfully submitted,

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